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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,515	07/02/2003	Kevin T. Stone	5490-000335	3533
27572 7590 09/28/2007 HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,515	Applicant(s) STONE ET AL.	
	Examiner Melanie Tyson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 19, 20, 22-27, 31, 32, 35, 39, 40 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) 25-27, 31, 32 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 19, 20, 22-24, 39, 40, and 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 09 August 2007.

Election/Restrictions

1. This application contains claims 25-27, 31, 32, and 35 drawn to a species nonelected with traverse in the reply filed on 31 July 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 53 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed subject matter "wherein the sidewall is substantially parallel to an axis of the anatomical engaging section" constitutes part of the human body, which does not fall within at least one of the four categories of patent eligible subject matter recited in 35 U.S.C. 101 (process, machine, manufacture, or composition of matter).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-5, 9, 39, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (Patent No. 5,868,789). Huebner discloses a suture anchor (see entire document) comprising a single unit (14; surgical steel or a bio-absorbable compound, column 4, lines 25-27) having a bone engaging section (32) formed along an axis (dotted line), a bone engaging structure (thread 36) defining a maximum diameter (column 5, lines 2-4), a suture engaging section (46) spaced axially from the bone engaging section (32) and defining a diameter less than the maximum diameter, an eyelet (50; Figure 6 shows a selected portion of a suture passes through and extends generally along the axis), and a suture passage (portion through eyelet 50) operable to allow a suture to enter and exit the suture engaging section from a single section (for example, at the left-most section of the suture engaging section) such that the selected portion of the suture remains substantially within the maximum diameter and substantially only through the suture engaging section (46). Figure 6 further shows the suture engaging section (46) is able to be substantially disposed below an exterior surface of a bony structure (114) after implantation.

5. Claims 1-9, 19, 20, 22-24, 39, 40, 42, 44, 45, and 47-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (Patent No. 5,851,219). Goble discloses a suture anchor (see entire document) comprising a single unit (unitary body 10 formed of bioabsorbable materials, column 4, lines 36-44) having a bone engaging section (12), a bone engaging structure (thread 16) defining a maximum diameter (for example, see Figure 1), a suture engaging section (14) spaced axially from the bone engaging section (12) and defining a diameter less than the maximum diameter, a first

eyelet and a second eyelet in a single wall of the suture engaging section ("top wall," or end surface 26) formed to allow a selected portion to pass through the suture engaging section (C-shaped portions on end surface 26), and a suture passage interconnecting the first and second eyelets (channels 38 and bore 36 form a U-shaped passage, i.e., a first passage section and a second passage section formed at an angle relative to each other to have an exterior angle of at least 90 degrees) operable to allow a suture to enter and exit the suture engaging section from a single section (for example, at the right-most section of the suture engaging section) such that the selected portion of the suture remains substantially within the maximum diameter and substantially only through the suture engaging section extending generally parallel to the bone engaging section, and allows a suture to be passed to an exterior at a point other than the first and second eyelets (for example, see Figure 1). Figure 8 further shows the suture engaging section is able to be substantially disposed below an exterior surface of a bony structure and the eyelet is substantially exposed after implantation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6, 7, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of Martello (Patent No. 6,168,598 B1). Huebner discloses a device as described above, however, fails to disclose the eyelet is substantially exposed and accessible after implantation of the suture anchor. Martello discloses a suture anchor (Figure 1) comprising a first eyelet (34) defined by an opening on a proximal face of a suture engaging section (unthreaded portion of shank 17 and up, which has a horizontal axis and a vertical axis), a second eyelet (32), and a passage (36) interconnecting the first eyelet (34) and the second eyelet (32). Figure 4B shows an embodiment in which the passage (52) interconnecting a first eyelet (52u) and a second eyelet (52L) defines an enclosed bore and is substantially parallel with the bone-engaging axis (58). Martello teaches the eyelet on the proximal face of the suture-engaging surface is exposed and accessible after implantation of the suture anchor (column 2, lines 11-15; see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made in order to place the eyelet of Huebner on a proximal face of the suture engaging section as taught by Martello such that the eyelet is exposed and accessible after implantation of the suture anchor in order to facilitate the procedure by eliminating the need for a multiplicity of specialized tools to attach sutures (column 2, lines 12-22).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of Martello as applied to the claims above, and further in view of Borzone et al. (Patent No. 5,814,070). Huebner in view of Martello discloses a device as described above, however, fails to disclose that the suture passage allows a suture to be passed to an exterior of the suture engaging portion at a point other than the first and second eyelets. Borzone et al. disclose a suture anchor (Figure 6) comprising a suture engaging section (36) and a bone engaging section (34). Borzone teaches a suture passage (38) that allows a suture to be passed exterior of the suture engaging section (column 4, lines 3-18). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the suture passage of Huebner in view of Martello as taught by Borzone et al. in order to distribute the stress on the suture material over the diameter of the distal end (column 4, lines 11-13), thus minimizing the risk of breakage of the suture material.

10. Claims 46 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of Martello as applied to the claims above, and further in view of Goble et al. Huebner in view of Martello discloses a device as described above, however, fails to disclose the eyelet includes a first and second eyelet formed through a proximal face, or top wall, of the suture engaging section and the suture passage interconnects the first and second eyelets. Goble discloses a suture anchor (see entire document). Goble teaches the first and second eyelets are formed through a proximal face and the suture passage interconnects the first and second eyelets such that the suture will not interfere with the inserter, the suture has the ability to slide once the anchor is installed

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in the bone, and such that the suture is protected from abrasion during anchor deployment and after anchor seating (for example, see column 2, line 62 through column 3, line 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the eyelets of Huebner in view of Martello as taught by Goble.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson 
September 24, 2007


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER